UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. RENÉE MARIE BUMB** **CIVIL NO. 19-2875 (RMB)**
THIS DOCUMENT RELATES TO ALL CASES	

TPP TRIAL PLAINTIFFS' REPLY BRIEF REGARDING WARRANTIES, ECONOMIC DAMAGES, AND MOTION *IN LIMINE* NO. 16

Plaintiffs submit this Reply in accordance with the Court's briefing instructions. (*See* 9/17/24 Tr., at 131:4-8 (giving Plaintiffs reply brief).) Defendants' response makes several important concessions. (Dkt. No. 2857 ("Defs' Br.").) First, Defendants do not argue that *scienter* is in any way relevant to Plaintiffs' express warranty claims or damages. Second, Defendants acknowledge that a "full refund" damages model is appropriate under a benefit-of-the-bargain inquiry when the product contains a fundamental defect (Defs' Br., at 1 ("unusable for its intended purpose")), or when the Defendant engaged in "blatantly illegal conduct[.]" (*id.*, at 9-10). The Court has previously found at the MTD stage, at class certification, and again at summary judgment, that the facts of this matter support the jury deciding whether Defendants' VCDs were economically worthless.[1]

A. The Defendants' VCDs Had a Fundamental Defect and Were Illegally Sold, and a Reasonable Jury Could Determine They Had Zero Economic Value

This case does involve a fundamental defect and "blatant"[2] conduct on the Defendants' part. The defense witnesses have all admitted that the NDMA and NDEA should not have been present at all, and the drugs should not have been sold,

[1] This was found recently by another Court in this District under very similar circumstances involving nitrosamine contamination of medication. *In re Metformin Mktg. & Sales Prac. Litg.*, No. 20-cv-2324 (D.N.J. Jan. 31, 2023) (Dkt. No. 251) (Arleo, J.) ("Plaintiffs have sufficiently . . . alleged that the contaminated MCDs [metformin-containing drugs] they paid for were worthless.").

[2] To be clear, "blatant" is Defendants' word, not a legal standard. Authorities cited by both sides show that illegally sold products have no legitimate value, regardless of whether the Defendants' conduct was "blatant."

and ZHP characterized the reason for the recall as "**an unacceptable carcinogenic risk** to the intended patient population." (*See, e.g.*, Pls' Opp'n to Defs' Omnibus SJ Statement of Material Facts, at ¶ 79 (citing documents) (emphasis added) (filed Jan. 22, 2024). In fact, ZHP's *own* cGMP expert conceded at his September 18, 2024 *Daubert* hearing that he agrees with the FDA Warning Letter's determination of cGMP violations, including the failure by ZHP to perform a proper risk assessment on its manufacturing process - thus impacting every pill ever sold - and that the contaminated pills "should not have been sold." (9/18/24 Tr., 44:3-9, 73:25-74:16, 118:2-4). This was the reason for the recall and import ban levied against ZHP. Every finished pill was necessarily adulterated by definition and therefore illegally sold, since ZHP violated cGMPs in the manufacture of the API. 21 U.S.C. §§ 331 & 351; (*see also* SJ Op., at 32 ("If the API is found to be statutorily adulterated, then the finished dose products were necessarily adulterated.")). The Court has indicated that if cGMP violations render the drugs adulterated as a matter of law, as found by the FDA in its Warning Letter which served as the basis for its import ban against ZHP, the jury will be so instructed. (9/18/24 Tr., 102:20-23).

The jury will also hear evidence that ZHP (and Torrent for a period of time) *knew* of the contamination yet continued to sell their pills.

B. <u>Defendants Dispute Their *Own* Authorities Regarding the Propriety of Zero Value/Full Refund Damages in Their Appendix B (Dkt. No. 2857-4)</u>

Defendants cite no authority in any jurisdiction that *forecloses* full refund or

zero value damages in express warranty settings. (Dkt. No. 2857-4 (Defs' App'x B).) As this Court recognized, this is a fact-dependent question and is not a bright-line rule. (9/10/24 Hrg. Tr., at 115:8-23 (agreeing with Plaintiffs' counsel that Defendants are "overstating" the law on this point).)

Defendants' Appendix B baselessly quibbles with the facts of the cases cited by Plaintiffs, while failing to affirmatively offer a single authority suggesting that full refund is a legally foreclosed remedy under the benefit-of-the-bargain damages measure in any express warranty subclass "b" jurisdiction.

Moreover, ***Defendants actually dispute their own prior descriptions of cases on this point***. For Mississippi, Montana, Nebraska, and New York, Plaintiffs' citations and parentheticals were pulled *directly* from Defendants' *own* express warranty chart submitted to the Court at the class certification stage. (*Compare* Dkt. No. 2857-4 *with* Dkt. No. 2008-7 (Defs' Express Warranty Chart as submitted at class certification including column regarding "Zero Value" theories).) For example, Defendants now chastise Plaintiffs' citation to a Mississippi authority as "mischaracterizing" the case (*see* Dkt. No. 2857-4, at 5), but Defendants themselves cited that very case with the *exact same* parenthetical when they told the Court at class certification that, "Yes," Mississippi courts ***do*** allow zero value theories for express warranty claims (*see* Dkt. No. 2008-7, at F-36.). This is also the case for Montana, Nebraska, and New York, where Defendants now dispute their own prior

acknowledgments of the law. Defendants' current criticisms of Plaintiffs' authorities on full refund or zero value express warranty damages theories are addressed, case-by-case, in a modified version of Defendants' own Appendix B (attached hereto as **Exhibit 1**). All express warranty jurisdictions allow full refund or zero value damages under the benefit of the bargain, and this Court got it right in its MTD, class certification, and summary judgment rulings in 2021, 2023, and 2024, respectively. (MTD Op. 2, at 8-13 (Dkt. No. 728); Class Cert. Op., at 88-89 (Dkt. No. 2261); SJ Op., at 20 & n.17 ("[T]he Court has expressly stated Ps worthlessness theory raises a genuine issue of material fact and leaves that for the fact-finder.").)

Defendants' criticisms of Plaintiffs' authorities fail to grapple with the issues here. First, Defendants try to distinguish a number of Plaintiffs' cases because they did not involve warranty claims. (Defs' Br., at 6.) Defendants fail to observe that all the authorities cited by Plaintiffs involved the *exact same* benefit-of-the-bargain damages measure, and authorized zero value damages in analogous factual contexts.

In addition, Defendants rely on irrelevant and distinguishable authorities (Defs' Br., at 3), which are addressed here:

- *Godec v. Bayer Corp.*, No. 10cv224, 2012 WL 1201013 (N.D. Ohio Apr. 10, 2012). This case involved Men's "One-A-Day" multivitamins that were sold with a claim that they promoted prostate health among other uncontested beneficial effects. The plaintiffs did not claim the vitamins were adulterated, contaminated, or defective, or otherwise claim that there was any harmful or safety-related fundamental defect with the product.
- *A&E Adventures LLC v. Intercard, Inc.*, 529 F. Supp. 3d 1333, 1340 (S.D. Fla. 2021). This case involved card swipe software and hardware that was used for

years by the plaintiff despite not having the full functionality desired, and the evidence showed that the plaintiff even made inquiries regarding purchasing further units and eventually resold the hardware units for nearly the full price paid for them. Plaintiffs here never resold VCDs, or willingly purchased *more* VCDs after the recalls. On the other hand, Plaintiffs' Florida authorities *Debernardis* and *Davis* are directly on point regarding adulterated medications having no economic value. (Pls' Br., at 10-11 (Dkt. No. 2844).)

- *Steel Dynamics Columbus, L.L.C. v. Altech Env't USA Corp.*, 734 F. App'x 234, 237 (5th Cir. 2018). Defendants cite this case, interpreting Mississippi law, addressing a plaintiff who received a defective emissions monitoring system for its factory from the defendant, and then received a credit from a third-party hired to fix the system for certain component parts in the defective system. This case is totally inapposite. No partial "fix" existed here. Each pill is a non-severable whole, and was contaminated with NDMA and/or NDEA. Indeed, the Federal Food Drug and Cosmetic Act requires a demonstration of both safety and efficacy, as well as continuing demonstrations of quality and purity through cGMP compliance. There is no way to credit out the component parts of a prescription pill, and the law does not allow this - the entire pill either can or cannot be legally sold based on the approved specifications - which never included NDMA or NDEA during the class period. This only highlights why the contamination here posed a fundamental defect entitling Plaintiffs to full reimbursement – it was non-severable. In addition, Defendants should be estopped from arguing their changed position that Mississippi law does not allow full refund damages, having so admitted at class certification, *see supra*.
- *Weaver v. Champion Petfoods USA Inc.*, 471 F. Supp. 3d 876, 881 (E.D. Wis. 2020), *aff'd*, 3 F.4th 927 (7th Cir. 2021). This Wisconsin case involved beef tallow ingredients in dog food that had tested positive for very low levels of pentobarbital, with no evidence that the finished dog food products actually sold contained *any* residual amounts of the chemical. Indeed, the defendant never even recalled the product because the levels in the dog food were not detectable. Moreover, the plaintiff did not purchase any dog food during the time period that the product was actually sold with the beef tallow in question. Genotoxin-contaminated prescription medicines intended for human consumption are quite different from uncontaminated dog food.
- *In re Rezulin Prods. Liab. Litig.* 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002); *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004); *Shahinian v. Kimberly-Clark Corp.*, No. 14-8390, 2016 WL 11722907, at *15 (C.D. Cal. Nov. 14, 2016). This Court has previously and repeatedly rejected Defendants' citations to *Rezulin*, *Heindel*, and *Shahinian*. (*See, e.g.,* SJ Op., at 65 & n.61 ("The Court states again as it has in other opinions that *Rezulin* is not apposite here."); *see*

also id. at 67 ("Such a probability the Court finds is more than a contra-indication, which is why *Heindel* and *In re Rezulin* are not on point. As the biological effects of the VCDs are Janus-faced, the Court finds support to have the fact-finder decide whether TPPs did or not get the benefit of the bargain."); *see also* Class Cert. Op., at 89 (in rejecting Defendants' *Daubert* argument as to Dr. Conti's worthlessness opinion, stating that "[t]his Court has also found that the cases defendants have cited – *In re Rezulin [] and Shahinian v. Kimberly Clark Corp.* [] – are not on point").)

- *Corbett v PharmaCare U.S. Inc.*, No. 21cv137, 2024 WL 1356220 (S.D. Cal. March 29, 2024). This case involved the use of black elderberry extract as a dietery supplement to promote immune system health. There was no evidence (or even allegation) that the product was not sold exactly as advertised or that it contained any undisclosed harmful contaminants. Plaintiffs' claim was merely that it was a new dietary ingredient and was thus technically illegal to have sold without first notifying the FDA. *Corbett* actually references cases cited by Plaintiffs (*In re JUUL*, *In re Morning Song*, *Steroid Hormone*) as examples of cases where full refund is appropriate.
- *In re Amla Litig.*, 320 F. Supp. 3d 578, 582 (S.D.N.Y. 2018). This was a product liability case that involved a hair relaxer "kit" that contained five (5) different components, only two (2) of which the plaintiffs contended were defective. The court in considering the plaintiff's unjust enrichment claim wrote that "there is no dispute that the conditioner, shampoo, and moisturizer in the kit perform their intended functions" and thus found that a "full refund would be unjust" on those facts. *Id.* at 591. Here, Plaintiffs never sought to certify unjust enrichment claims against Manufacturer Defendants. Also, the products in the kit were *severable* and each independently carried value. The approved, specified attributes allowing Defendants' VCDs sale were non-severable by definition - one could not purchase the efficacy but not the lack of quality and purity.
- *Caldera v. J.M. Smucker Co.*, No. CV 12-4936-GHK VBKX, 2014 WL 1477400, at *1 (C.D. Cal. Apr. 15, 2014). This case involved marketing products as "healthful" when they contained *disclosed* amounts of trans fats and high fructose corn syrup. Plaintiffs acknowledge a body of case law where food products were marketed as "premium" but were allegedly not premium, and courts did not endorse full refund theories because the plaintiffs received some value from their purchases. This case is completely different, as it involves *un*disclosed contaminants in FDA-approved medication that are acknowledged by all to be unacceptable, found to be adulterated by the FDA, precluding any sale (i.e., fundamental defects).
- *Zeiger v. WellPet LLC*, 526 F. Supp. 3d 652, 665 (N.D. Cal. 2021). This case involved premium dog food that allegedly contained lead and arsenic and BPA.

However, the evidence showed that the defendant's testing resulted in "non-detectable levels of arsenic and lead." *Id.* at 665. And further, the court rejected the plaintiffs' expert's contention that BPA was in fact dangerous. *Id.* at 671-72. Those facts are far from the facts here, where the contamination with cohort-of-concern genotoxins was established by the Defendants' own testing (requiring a recall and resulting in an import ban), and Defendants agree that this precluded them from selling the pills.

C. Defendants Offer Authorities that Support Plaintiffs' Contention that Dr. Conti Should Be Allowed to Affirmatively Opine as a Matter of Economics that Defendants' VCDs Had Zero Value

Defendants cite cases that support Plaintiffs' position that Dr. Conti should be allowed to affirmatively opine as to the economic worthlessness of Defendants' VCDs. (*See* Defs' Br., at 5 (citing authorities stating that Plaintiffs must be allowed to "show that the product she received has zero value").) And as a matter of balancing equities, since both experts are qualified and apply similar economic principles, if Dr. Stiroh is allowed to testify that Defendants' VCDs had economic value based on a theoretical, untethered theory that the claimed efficacy can be valued separately remainder of the defective and contaminated pill, which when discovered required their recall, Dr. Conti should be permitted to offer her opinion that these products carried no economic value.[3] The Court has already found, in denying Defendants' class certification *Daubert* challenge to Dr. Conti:

[3] As Plaintiffs clarified in their opening Brief, Dr. Conti assumed economic worthlessness as the basis for her full refund damages calculations, thus that is not a new assumption. The jury certainly may find that these products contained fundamental defects rendering them completely unfit for their intended purposes, and having no value.

> The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, i.e. mathematical model, which, … may reliably support her presumption of the worthlessness of the sold VCDs … The Court also notes defendants' motions did not defeat plaintiffs' arguments that Dr. Conti's "worthlessness" theory has already achieved validation in *BCBS v GlaxoSmithKlin*e … The *BCBS* Court found that not only was Dr. Conti's theory of "worthlessness" appropriate but also her methodology in adopting and justifying the theory was reliable.

(Class Cert. Op., at 88-89 (Dkt. No. 2261).)

D. <u>Defendants Argument that Plaintiffs' Labeling-Based Warranty Theory is "Not Viable" Even After Plaintiffs *Were Granted Summary Judgment*, Should Be Rejected</u>

The Court *granted* summary judgment to Plaintiffs, determining that the Defendants' labeling-based representations that the pills were the approved form of valsartan therapeutically equivalent to the brand reference drug, compliant with the compendial specifications and cGMP, constituted warranties as a matter of law. (SJ Op., at 29, 71.) Whether those warranties were breached was left to the jury. Despite having been granted summary judgment, Defendants argue that Plaintiffs' warranty theory is somehow "not viable" citing to *Harris v. Pfizer* and *In re: Avandia*.

Both *Harris* and *Avandia* are off-point, and *Harris* is no longer good law, as recognized by the MDL Judge who was tasked with revisiting the *Harris* decision. *In re Chantix (Varenicline) Mktg., Sales Pracs. & Prod. Liab. Litig*. (No. II), No. 22-MC-3050 (KPF), 2024 WL 2784234, at *16 (S.D.N.Y. May 28, 2024). In *Chantix*, the court found this litigation and others such as *In re Metformin* to be

properly decided, but distinguishable, as involving generic drugs, while *Harris* and *Chantix* involved the brand name drug CHANTIX® (*Avandia* also involved a brand drug). The *Chantix* court found that a labeling-based warranty of *therapeutic equivalence* is actionable for generic drugs (because they claim to be 'the same' as a branded drug), but not for the branded drug itself. *Id.* The court rejected the *Harris* court's express warranty decision, specifically finding that the plaintiffs may proceed with zero-value labeling-based cGMP express warranty,[4] implied warranty,[5] and consumer protection law claims. *Id.* at *24. In short, *Harris* is not helpful, is no longer good law, and *Chantix* actually supports the determination of warranties as a matter of law here.

Avandia is also of no help to Defendants. There, the court emphasized that the alleged warranty of absolute "safety and efficacy" was non-specific, that the Avandia label at the time did disclose significant cardiovascular risks, and the court emphasized that even after a black box warning was added, "Avandia remains on

[4] As to express warranty: "In particular, Plaintiffs have plausibly alleged that Defendant, by representing Chantix as FDA-approved, necessarily represented that Chantix was manufactured in accordance with certain cGMPs identified in the CAC and incorporated under state law." *Id.* at *25.

[5] As to implied warranty: "The Court must, at this stage of the litigation, credit Plaintiffs' well-pleaded allegations that a reasonable consumer would have expected the Chantix they purchased to have been free of contaminants and manufactured in accordance with the cGMPs, in addition to her broader expectation that Chantix perform in accordance with its clinical indications." *Id.* at *28 (citing, *inter alia*, *In re Valsartan*).

the market today." 588 F. App'x at 174, 176. The alleged warranty is *Avandia* and attendant facts are totally different from the warranties pursued here and which have been recognized as valid by *Chantix*, *Metformin*, and by this Court previously and in granting summary judgment to Plaintiffs.

E. Defendants Continue to Baselessly Attack IQVIA, Which is the "Gold Standard" and Best Available Evidence Which Generates a "Reasonable Estimate" of Classwide Damages

There can be no dispute that IQVIA is the gold standard of data sources for pharmaceutical cases. Defendants cite no case where IQVIA has been found unreliable. Plaintiffs cannot prove a negative.

Indeed, beyond the cases Plaintiffs' have cited[6] where the courts explicitly discuss the use of IQVIA, there are even more[7] cases where IQVIA data has been utilized, including cases where both the Plaintiff and the Defendant are pharmaceutical companies. Defendants cannot prevent Plaintiffs from using the very "benchmark" data source (as ZHP's corporate representative described the pricing

[6] Defendants' belabored attempts to distinguish Plaintiffs' IQVIA cases illustrate that IQVIA is the market leader for data regarding pharmaceutical companies. This data is used in litigation so often it does not even bear much discussion, and there are no other competing data sources that come even close to IQVIA for this purpose.
[7] *See, e.g., Bial-Portela & CA S.A., et al v. Alkem Laboratories Limited et al,* Case No. 19-304 (D. Del.) (Dkt. No. 95 (discussing the multitude of IQVIA products used in the litigation)); *Exeltis USA, Inc., Laboratorios Leon Farma, S.A., et al. v. Lupin LTD et a*l., Case No. 22-cv-00434 (D. Del.) (Dkt. No. 234-1, at 114 (making requests for Xponent PlanTrak Data and all IMS or IQVIA data); *Upsher-Smith Laboratories, Llc v. Zydus Pharmaceuticals (Usa) Inc. et al.*, Case No. 1:21-cv-1132 (D. Del.) (Dkt. No. 98 (issuing subpoenas requesting IQVIA Xponent Data)).

and other data from IQVIA) that appears to power their entire industry and is used regularly by *these* Defendants SEC filings for this very purpose.[8] Defendants' effort to malign IQVIA by indicating it is primarily used in research activities, even if true, actually reinforces its reliability; that is exactly what Rule 702 contemplates as a reliability test.

It bears repeating that class damages models need not be subject to exact precision. *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 484 (3d Cir. 1998) (damages may be proven with a "reasonable estimate, as long as the jury verdict is not the product of speculation or guess work" (citations and quotations omitted)); *see also Thorogood v. Sears, Roebuck & Co*., 547 F.3d 742, 748 (7th Cir. 2008) ("Aggregate class proof of monetary relief may be based on sampling techniques or other reasonable estimates, under accepted rules of evidence." (citing and quoting authorities)); *Bell Atl. Corp. v. AT&T Corp*., 339 F.3d 294, 304 (5th Cir. 2003) (plaintiffs required to present a model that will yield "a just and reasonable estimate of the damages.").

IQVIA itself states that its data is a reasonable approximation of market

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[8] *See, e.g.,* https://www.sec.gov/Archives/edgar/data/818686/000119312523031250/d443725d10k.htm (Teva stating in Form 10-K that "Market data, including both sales and share data, is based on information provided by IQVIA, a provider of market research to the pharmaceutical industry ("IQVIA")") (last accessed September 26, 2024).

activity and is "highly reliable" for research applications including for pricing data. Dr. Conti's use of IQVIA Xponent pricing data does precisely that – it provides a just and reasonable estimate from which a jury may award damages.[9]

F. Defendants Undercut their Own MIL 16 Arguments

As part of Defendants' shotgun effort to create a mirage of authority, Defendants themselves cite cases undercutting their so-called "replacement drugs" defense. In the *Godec v. Bayer* case involving multivitamins, the court rejected Bayer's similar "replacement" vitamin theory as simply "not part of the calculus" under benefit-of-the-bargain, as follows:

> Bayer also argues that Godec has no damages because the vitamin he now purchases (and purchased before he switched to Bayer's Men's Health)—a GNC vitamin—is more expensive than the Men's Health vitamin he bought from Bayer. But as explained both above and in the ruling on class certification (and as Bayer repeatedly argues), the proper measure of damages for a breach of express warranty in Ohio is the value of the product as represented less the value of the product as received … Except perhaps to the extent that it may help in determining

[9] Defendants aver that Dr. Conti did not use IQVIA data in the *BCBS* matter. That matter ultimately was not sought to be certified as a class action, and therefore there was no need to model damages for absent class members, as there is here. Accordingly, Dr. Conti ultimately used the named plaintiffs' own claims data. Nevertheless, IQVIA data was considered and used for other purposes in that case. Dr. Conti also used IQVIA pricing data in *Actos*. *In re: Actos Antitrust Litig.*, No. 1:13-CV-09244 (RA) (SDA), 2024 WL 4251891, at *24 (S.D.N.Y. Aug. 9, 2024) (stating that using "IQVIA Xponent [pricing] data of retail sales to identify purchases made by class members, Conti calculated the gross overcharge paid by putative class members … Conti has demonstrated that the IQVIA [Xponent pricing] data can be used to reliably identify class purchases on a classwide basis").

> the value of Bayer's vitamins as represented or received, **the cost of another vitamin is simply not part of the calculus** … Accordingly, summary judgment against Godec is inappropriate.

Godec v. Bayer Corp., No. 1:10-CV-224, 2012 WL 1201013, at *4 (N.D. Ohio Apr. 10, 2012) (emphasis added).

Plaintiffs largely rest on their prior MIL 16 briefing which makes the same point made by the *Godec* court. (Dkt. No. 2822, at 1; Dkt. No. 2811.) Not only are replacement drugs "not part of the calculus," their consideration would in fact create a law of no damages in warranty cases. The Court correctly rejected this defense at the September 9, 2024 CMC, just as the Court had previously rejected the defense in its well-reasoned summary judgment opinion (SJ Op., at 61-62), and just as other courts have reached the same result in defective product cases where damages are measured in relation to the value or lack thereof of the product as sold, not as part of a market impact damages theory as is often used in antitrust or RICO cases.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 27, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s John R. Davis